K090183

510(k) Summary

SEP 25 2009

Name:	Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, NC 27105
Phone:	336-744-0157
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Contact Person:	Tiffanny A. Thomas, Global Regulatory Affairs Specialist
Date:	January 23, 2009
Trade Name:	Hercules 3 Stage Wire Guided Balloon
Common Name:	Balloon Dilation Catheter
Classification Name:	Esophageal Dilator (21 CFR 876.5365, Product Code 78 KNQ)
Legally Marketed Devices:	Quantum T.T.C Balloon Dilation Catheter (K935094)
Description of the Device:	The modified Hercules 3 Stage Wire Guided Balloon consists of coaxial catheter with a dilation balloon mounted on the distal tip. The balloon is inflatable with fluid to three distinct and progressively larger size diameters to exert pressure on strictures and affect dilation of the stricture. It is offered in a variety of balloon diameters. Supplied sterile and Intended for Single Use. Inflation device sold separately.
Intended Use:	Used to dilate strictures of the gastrointestinal tract, including strictures of the esophagus, pylorus, duodenum and colon.
Comparison of Characteristics:	We believe the proposed device to be substantially equivalent to currently marketed predicate device. We believe the proposed device to be substantially equivalent to the named predicate in terms of Intended Use, the same fundamental design and operational principle and fundamental scientific technology.
Performance Data:	We believe risks associated with the modifications to the subject device to be adequately addressed through our Design Control Process.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 25 2009

Ms. Tiffanny Thomas
Global Regulatory Affairs Specialist
Cook Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K090183
Trade/Device Name: Hercules 3 Stage Wire Guided Balloon
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Codes: KNQ
Dated: August 26, 2009
Received: August 27, 2009

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090183

Device Name: Hercules 3 Stage Wire Guided Balloon

Indications for Use:

Used to dilate strictures of the gastrointestinal tract, including strictures of the esophagus, pylorus, duodenum and colon.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090183